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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR         | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|--|-------------|------------------------------|-----------------------|------------------|
| 10/533,411   | 10/17/2005  | Michael Brian Edward Bremner | 1171/42784/157-PCT-US | 9055             |
| 279 7590 06/09/2009<br>TREXLER, BUSHNELL, GIANGIORGI,<br>BLACKSTONE & MARR, LTD.<br>105 WEST ADAMS STREET<br>SUITE 3600<br>CHICAGO, IL 60603 |             |                              |                       |                  |
| EXAMINER   |             |                              |                       |                  |
| OSTRUP, CLINTON T  |             |                              |                       |                  |
| ART UNIT   |             | PAPER NUMBER                 |                       |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/533,411

**Applicant(s)**

BREMNER ET AL.

**Examiner**

CLINTON OSTRUP

**Art Unit**

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02/24/09 & 4/27/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 17, 26-39, 42 and 45-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 17, 26-39, 42 and 45-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/29/05 & 5/6/08 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office Action is in response to the amendments filed February 4, 2009 and April 27, 2009. As directed by the amendment filed February 4, 2009, claims 1 and 31-36 have been amended, claims 2-16 and 18-25 have been cancelled and claims 37-51 have been added. Claims 1, 38, 50 and 52 were further amended and claims 40-41 & 43-44 were cancelled in the amendment filed April 27, 2009.
2. Thus, claims 1, 17, 26-39, 42, and 45-51 are pending in this application.

### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Figures 1, 2 & 9 are the only figures showing an open tubular section with a port and none of these figures show an open tubular section with a port with a filter covering the housing. Therefore, the "port" or the "filter covering said housing" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 17, 26-39, 42, and 45-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon et al (6,272,933) and further in view of Wittmaier et al. (4,366,821).

Gradon discloses a system (figure 5) for delivering a supply of gases to a patient (13) comprising: a gases supply (1) providing a flow of gases (indicated by arrow in tube 6), a humidifier (10) receiving said flow of gases from said gases supply and capable of humidifying (via 4) said flow of gases up to a level of humidity prior to delivery to said patient (13), a conduit (43 & 44) conveying said flow of gases from said humidifier (10) to said patient (13), a sensing device (figure 3 encompassing the releasable tube 42 with a port 41 and sensing probe 19) to sense the humidity (See: col. 13, lines 48-57), temperature (via 34) or flow rate (via 35) of said flow of gases after said flow of gases

have been humidified by said humidifier (10), said sensing device comprising a cartridge (42) or open tubular section (42) having a port (41), a sensor (34 & 35), a housing (19) releasably (it is possible to take the sensors 34 & 35 out of 19 (See: col. 9, lines 1-38)) containing said sensor (34 and 35), in use said housing (19) being sealably connected to the port (41), and wherein the cartridge (42) or open tubular section (42) is releasably coupled (42 to 43 and 42 to 44), in use, in line between said humidifier (10) and said conduit (43 & 44), the sensor (34 & 35) being coupled to said cartridge (42) or open tubular section (42) such that said sensor (35 & 35) is exposed to said flow of gases through said cartridge (42) or open tubular section (42).

However, Gradon lacks specifically teaching a filter covering the housing and the filter being located such that said sensor is exposed to a portion of said flow of gases passing through said filter only, with a significant portion of the flow of gases passing from the humidifier to the conduit without passing through the filter material.

Wittmaier teaches a breath monitor device (figure 2) with a sensor (14) positioned in the path of the breath flow (inside 12) and covered with a filter (27 screen or perforated portion) which would have the exposed to a flow of gasses through a filter material (27) with the filter material (27) being located such that the sensor (14) is exposed to a portion of the flow of gasses passing through the filter material only, with a significant portion (portion that does not go through 27) of the flow of gasses passing directly through without passing through the filter material.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the filter material (27) as taught by Wittmaier,

surrounding the sensor housing in the humidification system disclosed by Gradon, in order to obtain a humidified gas delivery system that utilizes a filter material to reduce condensation from accumulating on the exposed surfaces of the sensor housing.

Regarding claim 17, Gradon discloses a humidifier (10) with a humidification chamber (4) adapted to receive a volume of water (8) and a water heater (9) that heats the water. The flow of gases passes through the humidification chamber, via a gases inlet (3) and out via a gas outlet (12) and the flow of gases is humidified by evaporating water. See: col. 7, lines 64-66.

Regarding claim 26, Gradon discloses a humidifier (10) with a controller (11) to control the water heater (9) and the level of humidity or temperature of the flow of gases flow. See: col. 7, lines 50-63.

Regarding claim 27, Gradon discloses sensors (34 & 35) that are connected to a controller (11) and conveys a sensed level of humidification of the flow of gases to said controller, and the controller controls the water heater (9) to alter said sensed level of humidification of said flow of gases to a predetermined humidification level. See: col. 13, line 58 - col. 14, line 20.

Regarding claim 28, Gradon discloses a gas outlet temperature of 37°C and containing 44 mg of water vapor per liter, thus meeting the predetermined humidification level as claimed. See: col. 14, lines 4-13.

Regarding claim 29, Gradon discloses connections formed on the open tubular section (42) wherein one side is connected to the humidifier (via 43) and the other side

is connected to a conduit (via 44) that leads to a patient. See: col. 10, lines 28-47 and figures 3 & 4 wherein the tubular connector is connected to 43 & 44.

Regarding claims 30 & 51, Wittmaier teaches connections (24) that are friction fittings. See: figure 2.

Regarding claims 31 & 50, Gradon discloses a sensing device (figure 3) to sense humidity (See: col. 13, lines 48-57), temperature (via 34) or flow rate (via 35) of a flow of gases (indicated by arrow in tube 6) in a conduit (43 & 44) after said flow of gases have been humidified (via 10) by a humidifier (10) and providing feedback (Figure 6) to a controller (11) which controls said humidifier (10), said sensing device (figure 3) comprising: a cartridge (42) or open tubular section (42) having a port (41), a sensor (34 & 35), a housing (19) releasable (34 & 35 can be removed from 19) containing said sensor (34 & 35), in use said housing (19) being sealably connected to the port (41), and wherein said cartridge (42) or open tubular section (42) is releasably coupled (42 to 43 and 42 to 44), in use, in line between the humidifier (10) and the conduit (43 & 44), the sensor (34 & 35) being coupled (via 41) to said cartridge (42) or open tubular section (42) such that said sensor (34 & 35) is exposed to said flow of gases through said cartridge (42) or open tubular section (42), and Wittmaier teaches a breath monitor device (figure 2) with a sensor (14) positioned in the path of the breath flow (inside 12) and covered with a filter (27 screen or perforated portion) which would have the exposed to a flow of gasses through a filter material (27) with the filter material (27) being located such that the sensor (14) is exposed to a portion of the flow of gasses passing through the filter material only, with a significant portion (portion that does not

go through 27) of the flow of gasses passing directly through without passing through the filter material.

Regarding claim 32, Gradon discloses a housing (19) containing a sensor (34 & 35), and the housing extending through or residing within the open tubular section (42) and at least part of said housing being exposed to the flow of gases.

Regarding claims 33, 38 and 46 Wittmaier teaches the filter material (27) is a semi-permeable (screened or perforated) material. See: col. 3, lines 30-33.

Regarding claims 34, 39 and 47 Wittmaier teaches a filter material that is a porous (27 is screened or perforated) media and modification of sizes or the perforations is well within the skill of having ordinary skill in the art and one skilled in the art would preferably make the perforations in the micron level to prevent bacteria from contacting the sensor.

Regarding claims 35-36, 48-49 Wittmaier teaches a sensing device (figure 2) wherein the sensor (14) has a heating element (30) attached to the housing (12 & 26), which would provide heat to the sensor.

Regarding claims 37, 45 Wittmaier teaches a filter material (27 of Wittmaier) that would be used to cover the port (41 of Gradon).

Regarding claim 42, Gradon discloses a system wherein the housing (19) extends through or resides within said cartridge (42) or open tubular section (42) and at least part of said housing (bottom part) is exposed to said flow of gases.



***Response to Arguments***

7. Applicant's arguments filed February 24, 2009 have been fully considered but they are not persuasive.
8. Applicant argues that the sensors of Gradon are encased or encapsulated within housing and therefore there is not teaching or suggestion that the sensor may be removed/released from the housing to allow the housing to be disposed of, thereby allowing the sensor to be used for different patients, while avoiding cross-contamination between patients.

First, these arguments are not commensurate with the scope of the claims. The claims merely require "a housing releasably containing said sensors." Since the sensors of Gradon can be released from the housing (even if it is done forcibly and destroys the sensors and/or housing, they are releasable from the housing), and there is no requirement that the sensors be functionally preserved and/or used in other housings.

However, even if such a limitation were included into the claims, it has been held that the separation of elements, where removability would be desirable, is a design consideration within the skill of the art. *In re Dulberg*, 283 F.2d 522, 129 USPQ 348 (CCPA 1961). In the instant case, it would be desirable to recycle the both the expensive sensor components and plastic housing in order to decrease waste thereby helping reduce the negative impact on the environment. Moreover a housing is generally referred to as "a shelter; covering" (See: Webster's New World Dictionary, Third College Edition definition of housing) and is therefore suggestive of a releasable environment.

Secondly, Gradon clearly contemplates that components of the device can be integrally moulded or manufactured separately and then be attached together. See: col. 10, lines 22-27 and 32-35. Thus, the skilled artisan would clearly, by simply reading the disclosure of Gradon, reasonably expect that a housing (19) could be manufactured with the sensors integrally moulded into the housing of the housing and sensor components manufactured separately and then releasably attached together to form sensing devices that would be reasonably expected to work equally well.

Regarding applicant's arguments that Wittmaier does not describe a sensor element being contained within a housing which engages with the sideways tubular portion, the examiner reminds applicant that the rejection is based upon a combination of references and Wittmaier was used for its teaching of a filter covering the housing and the filter being located such that said sensor is exposed to a portion of said flow of gases passing through said filter only, with a significant portion of the flow of gases passing from the humidifier to the conduit without passing through the filter material.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bell (6,039,696) which teaches a removable humidification sensor for use in a ventilation system that has a selectively water vapor permeable membrane.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771